

REPORT OF STUDY RELATED COMPLAINT

Please complete form electronically, print out and submit signed copy. Report may be forwarded to the IRB chair electronically but must be followed by a signed hard copy.

Date of report:

Title of study:

DMHAS Study ID Number:

Principal investigator

Name and Title:

Phone:

Fax:

E-mail:

Date of complaint:

Date investigator became aware of
complaint:

Study site involved:

Description of complaint:

Where applicable, please describe action taken to ameliorate any discomfort or negative consequence related to the complaint:

Where applicable, please describe action taken to reduce/eliminate likelihood of recurrence:

Does the nature of the complaint suggest/require a change in study protocol and/or consent form? ☐ yes ☐ no

Description of any action planned or taken as a result of complaint such as internal procedural change; intervention with research staff; consent form change; protocol change; etc:

Is IRB approval of a revision required with relation to any proposed changes?
☐ yes ☐ no

Principal Investigator – Signature

Date